NOV - 9 2000

510(k) Summary 100S/100LC/485 Anser Pie Medical

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent 8000 Castleway Drive Indianapolis, IN 46250

Phone:

(317) 849-1916

Facsimile:

(317) 5779070

Contact Person:

Colleen Hittle

Date:

July 21, 2000

807.92(a)(2)

Trade Name:

100S/100LC/485 Anser Ultrasound Imaging Systems

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulsed doppler imaging system

892.1550

Ultrasonic pulsed echo imaging system

892.1560

Classification Number:

90IYO

807.92(a)(3)

Predicate Device(s)

Pie Medical

480

K911584

250

K915647

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary 100S/100LC/485 Anser Pie Medical

807.92(a)(5)

Device Description

Intended Use(s)

Pie Medical's 100S/100LC/485 Anser ultrasound systems used are to perform general diagnostic ultrasound studies.

510(k) Summary 100S/100LC/485 Anser Pie Medical

Comparison Chart for Substantial Equivalence

Musculosketal		Muscuiosketal						
Fetal		Cardiac	Musculoskeletal					
Peripheral Vascular		Peripheral Vascular	Intraoperative				•	
Pediatric		Intraoperative	Peripheral Vascular					
Neonatal Cephalic		Transrectal	Pediatric	Fetal		Neonatal Cephalic		
Intraoperative		Small Organs	Transrectal	Peripheral Vascular	Intraoperative	Intraoperative		
Transrectal	Fetal	Pediatric	Small Organs	Pediatric	Small Organs	Small Organs		
Transvaginal	Pediatric	Fetal	Fetal	Intraoperative	Pediatric	Pediatric		
Small Organ	Small Organ	Transvaginal	Transvaginal Cardiac	Small Organ	Fetal	Fetal	Transrectal	
Abdominal	Abdominal	Abdominal	Abdominal	Abdominal	Abdominal	Abdominal	Urological	Applications
3.5 – 8 MHz	3.5 – 7.5 MHz	3.5-8MHz	3.5-7.5 MHz	3.5-7.5 MHz	3.5 – 7.5 MHz	3.5 – 7.5 MHz	5.0 - 7.5 MHz	Frequencies
B, B+B, B+M, M	B, B+B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	Modes
					Annular			
				Linear	Mechanical			
		Curved		Curved	Curved			
Curved/Linear	Linear	Linear	Annular	Annular	Linear	Linear	Annular	Technology
					K900469)	K874192)	(K911043)	
this submission	cleared via 510(k) 911584	this submission	this submission	K915647	cleared via	1150, cleared via	Probe	
To be cleared with	(Predicate to 485 Anser,	To be cleared with	To be cleared with	to 240, cleared via	(Predicate to 250,	(Predicate to	Endorectal	
PIE 485 Anser	PIE 480	٠.	PIE 100S	PIE 250 (Predicate	PIE 1150	PIE 400/450	Pie MERA	



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

NOV - 9 2000

Pie Medical c/o Colleen Hittle Official Correspondent The Anson Group 800 Castleway Drive Indianapolis, IN 46250

Re: K002357

100S,100LC, and 485 Anser Ultrasound Imaging Systems

Regulatory Class: II

21CFR892.1560/Procode: 90 IYO 21CFR892.1570/Procode: 90 ITX

Dated: October 30, 2000 Received: October 31, 2000

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ultrasound systems listed below, as described in your premarket notification:

Transducer Model Numbers for the 100S Ultrasound Imaging System

402144

402154

402155

402156

Transducer Model Numbers for the 100LC Ultrasound Imaging System

Transducer Model Numbers for the 485 Anser Ultrasound Imaging System

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Page -3- Ms. Hittle

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.

Captain, USPHS

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure(s)

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

				<u>, , , , , , , , , , , , , , , , , , , </u>		Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		Е	E	·					E -	
Intraoperative Abdominal									e services	
Intraoperative Neurological								· · · · · · · · · · · · · · · · · · ·	15 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	yr 12 10 Ask
Pediatric		Е	E						Е	
Small Organ (specify)		Е	Е					s in the second	E Disease and the control of the con	an yerek
Neonatal Cephalic		N	N						N	
Adult Cephalic								er troping to have	The control of the second second	500° ja
Cardiac		N	N					er at the	N That is the contract	s, welv
Tranesophageal								1881 - 1881 -	nemis kilomas	1.00
Transrectal		Е	E						E	
Transvaginal		Е	Е					194 Jul	E este strategi	al relier gase
Transurethral					**************************************					
Intravascular									. Francisco	territorio de la composição
Peripheral Vascular									r ne super	
Laparoscopic										
Musculo-skeletal Conventional									. 244	Mercy Are
Musculo-skeletal Superficial										7
Other	lİ	· · · · · · · · · · · · · · · · · · ·	<u> </u>							

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

V		X/11	6 81	m
Prescription Use(FLEASE DO'N	OT WRITE BELOW THIS	I INE-CONTINUE ON ANOTHER PACE IS	VI IN	<u> </u>
(Per 21 CER 801, 109)	TOT WINTE BEEGW TING	END-CONTINUE ON ANOTHER PAGE IF	NEEDED)	

Concurrence of CDRH, Office of Device Evaluation (One)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>KOC</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	f Operation	 	,	
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		Е	E						E	
Abdominal		E	Е						E +	
Intraoperative (specify)									intervisional etievisional	Control (Control (Con
Intraoperative Neurological										
Pediatric		Е	Е						E	
Small Organ (specify)								114. (Apr.15.1.21.6)	tion of the transfer was to a	eg en en en Settada
Neonatal Cephalic										
Adult Cephalic								e in eustañ si astend	tega tekni er i gegeçle di	* . * *********************************
Cardiac		N	N					া কথা এনাই প	N Construction of London and	ere e la la transporte
Tranesophageal								200	e a tua especia	1.50000
Transrectal				-						
Transvaginal								10 system (404)	्राज्यात अन्यवस्थानुद्रका	man y
Transurethral										
Intravascular								A	s nah trat du	un til er er det judig.
Peripheral Vascular									7,8744,879	
Laparoscopic										
Musculo-skeletal Conventional									152 - 154	e e e
Musculo-skeletal Superficial					,					
Other		<u> </u>		1						

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Applicable Combined Modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>K002357</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						Е	
Abdominal										
Intraoperative (specify)									1907ko3	28-3,5
Intraoperative Neurological								a servid	a taken tan maka	t same a ma
Pediatric										
Small Organ (specify)		E	Е					national transcription and	E	e i Nijir wit say
Neonatal Cephalic										
Adult Cephalic								Alexander - Alexan	. The second second second	المهران الحراب الماسان
Cardiac								, e et tosse tiljatik	er om elektris til stålag al	and the second
Tranesophageal								ath a mile in tagents	om todalar o og talenskelskal	, es el proces sa
Transrectal										
Transvaginal	1	E	Е					an againtan an an an	Enter Granting	. 1.1
Transurethral	-									
Intravascular									2 cm 18 18 18 18 18 18 18 18 18 18 18 18 18	e milion nastru
Peripheral Vascular	1						,		N -1963	on to the sea
Laparoscopic										
Musculo-skeletal Conventional Musculo-skeletal										
Superficial										•
Other		L				<u> </u>	<u> </u>			<u> </u>

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments:	Small Organs (specifically, thy	roid, testicles, and breast);	Applicable Combined Modes:	B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number_

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		Е	Е						E	
Abdominal		E	Е						E &	
Intraoperative (specify)								594 S./	green from	6, 6, 6, 6, 6, 6, 6, 6, 6, 6, 6, 6, 6, 6
Intraoperative Neurological										
Pediatric		E	E					W. X. W	E	0.000
Small Organ (specify)		Е	Е					o est of the structures by displayed	E	a trobase
Neonatal Cephalic		N	N						N	
Adult Cephalic								the contract some significant	reconstruction of the contract	n in the term we have
Cardiac								State to Sure of Salt	a to the good and the standard	
Tranesophageal								n kana mekhirika	sumumierinista. m. kassuss	GARLESTE
Transrectal										
Transvaginal						,		est face and a	totto um el emergencia se	.er Lette
Transurethral					-				The state of the s	The street of th
Intravascular									Market and the state of the sta	en ji kasya
Peripheral Vascular									- M	and the second
Laparoscopic									1.00	New Property
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										•
Other								<u> </u>		<u></u>

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

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benediation I lea	Concurrence of CDRH, Office of Device Evaluation (ODE) (Division Sign-Off)

Prescription Use. (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENI and Radiological Devices

510(k) Number <u>K002357</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		-		,		Mode o	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal									4 -	
Intraoperative (specify)									e e e e e e e e e e e e e e e e e e e	The second secon
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		Е	E					Core (Albania) esp	E 19 1 - 14 12 1 19 19 19 19 19 19 19 19 19 19 19 19 1	in in Halfantal) Aa
Neonatal Cephalic									·	-
Adult Cephalic								14 - 1987 - 14 MARCH	and the second s	. Harris of Marks
Cardiac								5 7 mg	t en total Signa Albania Signa Sig	
Tranesophageal								mwii sed	tina i estimuest	e a setuation
Transrectal		Е	Е						E	
Transvaginal									- ಆಗಳಿಂಗಾಡಿ	er viz Egreso
Transurethral	1									
Intravascular									54 C / 1	
Peripheral Vascular	1								Page 1	i di mana na
Laparoscopic										and the second
Musculo-skeletal Conventional										
Musculo-skeletal Superficial	<u> </u>									,
Other]	<u></u>	1	1		l

N= new indication: P= previously cleared by FDA; E= added under Appendix E

and breast); Applicable Combined Modes: B+B; B+M
David h. Segram
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e of Device Evaluation (ODE)
(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices 510(k) Number <u>KOD 2357</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

			<u> </u>			Mode o	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									,	
Fetal		E	E						Е	
Abdominal		E	E						E	
Intraoperative Abdominal		N	N						N Maria	
Intraoperative Neurological										
Pediatric		E	Е					O. 1 1884 J	n E - nya sasara	- 1,5
Small Organ (specify)		Е	Е						E	
Neonatal Cephalic		N	N					" "No. + 12, 1200 (1976)	N	
Adult Cephalic								শার্থা ক্রান্তর্গ		
Cardiac		N	N					200 Jan 1824	N	
Tranesophageal				1						
Transrectal	\vdash	Е	Е						E	
Transvaginal		Е	Е					say mas	E service segmentations	V. N.
Transurethral	-								Light Control of the	
Intravascular									nest gas on sær	
Peripheral Vascular		E	E						Е	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication: I	P= previously c	leared by FDA:	E= added under	Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use	Division of Reprod

(Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>KOD 2357</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal		Е	E						E			
Abdominal		Е	Е						Е	are the second		
Intraoperative Abdominal									194.49 14.11			
Intraoperative Neurological												
Pediatric	1	E	Е						E			
Small Organ (specify)								5 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	of out of the occasion	e talle e to to see		
(specify) Neonatal Cephalic												
Adult Cephalic									and the state of t			
Cardiac		N	N					1. A.S.	N			
Tranesophageal								. 178.4	1 Tribbas	tribes of a		
Transrectal												
Transvaginal									That was a stage.	e e e e e e e e e e e e e e e e e e e		
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Intravascular	-							`	erena eser	and the second		
Peripheral Vascular									*6	1. 1. 1. 1. 1. 1.		
Laparoscopic										al es		
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other		1						<u>. L</u>	<u></u>	<u></u>		

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined modes = B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)

Prescription Use _____ (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>K00235</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic							•				
Fetal		E	E						Е		
Abdominal		Е	E						E	. New Y	
Intraoperative (specify)								·	. v jak 4 (M	าแบบกัญและ กล	
Intraoperative Neurological									Sales Constitution	. in the Mark Top Assertion of	
Pediatric		E	E					11.1.00/2	E committee and	100000000000000000000000000000000000000	
Small Organ (specify)								er e som	air is garantida an air		
Neonatal Cephalic											
Adult Cephalic								or an interesting of	alin i kenaliyatiyat darifti	ng kanadaga san r	
Cardiac								o i Silveto ajtigi	tanggan Notes S	e en la colonia de la colonia	
Tranesophageal								the state of the second		er was pes	
Transrectal	1	1									
Transvaginal								the second	The STANCE CONTRACT	. knudungs	
Transurethral									tu t		
Intravascular									Mark to the	on a surjection task	
Peripheral Vascular									, Va		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial										·	
Other				1	<u> </u>		1			<u> </u>	

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N = new	indication.	P= previously	cleared by	' FDA: E=	added under	Appendix	Ľ

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K002357

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		E	E						E		
Abdominal	-	E	E						E ,	+92	
Intraoperative (specify)						·				en nere en en	
Intraoperative Neurological					<u> </u>						
Pediatric	1	Е	E					(4,4)	*E - 1.2***********	Liu engpe de, ni	
Small Organ (specify)											
(specify) Neonatal Cephalic											
Adult Cephalic								<	er e verdrouwaa ka sii sa ka	este e questi	
Cardiac		N	N	<u> </u>				ক save 1 - 21 1 - 1 - 1 বিশ	N	حارب الأخوارد ال	
Tranesophageal											
Transrectal											
Transvaginal								and a sign task	t i de	in in new jirothi.	
Transurethral								39-5- () ()	ergani engangan	in some stage	
Intravascular								124 1	Yas Wing and Seas	. Harrista turk	
Peripheral Vascular	1			1					ren'n wewe	tt steet	
Laparoscopic											
Musculo-skeletal Conventional Musculo-skeletal										; .	
Superficial					ļ					•	
Other		<u></u>			<u> </u>	<u> </u>	<u> </u>	<u></u>	<u> </u>	<u> </u>	

N	N= new indication: P= previously cleared by FDA; E= added under	Appendix E
A	Additional Comments:	
A	Applicable combined modes: B+B; B+M	Lownol G. Stylm- e-continue on another page if needed)
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	Concurrence of CDRH, Offi	ice of Device Evaluation (ODE) (Division Sign-Off)

Prescription Use _____ (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number 1002357

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal												
Abdominal		E	E						E 2004			
Intraoperative Abdominal		N	N						N (1.756-144	e en la generate		
Intraoperative Neurological												
Pediatric		E	Е					- 78.8°	*E	The section of the second section of		
Small Organ (specify)		E	Е					indistruit	E			
Neonatal Cephalic		N	N						N			
Adult Cephalic								ethylander i eur	Karaman sa maya besar ten	ing of the said		
Cardiac		1						egel na tre en egy d	Marine de la companie	ita jakwa		
Tranesophageal												
Transrectal	-		+	1				escalible an	CONTRACTOR OF THE STATE OF THE			
Transvaginal								219 3.	Minimus and and a second	Programme Section 1999		
Transurethral								. 17	1 1-22 1-27 1-22 1-22 1-22 1-22 1-22 1-2	- 1-5 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		
Intravascular	 								n en en rance	e egy mentegetik		
Peripheral Vascular		Е	E						E	No. Carteryon		
Laparoscopic												
Musculo-skeletal Conventional									P1.			
Musculo-skeletal Superficial				-					9	.•		
Other												

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)	
Applicable combined modes: B+B; B+M	Varial G. fine

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>K00 2351</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		N	N						N		
Abdominal		E	E						E		
Intraoperative Abdominal									i in the second of the second	pump - a,	
Intraoperative Neurological											
Pediatric		E	E						E		
Small Organ (specify)								ora, erasista		•	
(specify) Neonatal Cephalic	İ										
Adult Cephalic								n er rege gar se	al professional supersection of the supersecti	te grand a grade	
Cardiac								Server to the	, to the stronger in dealer.	· · · · · · · · · · · · · · · · · · ·	
Tranesophageal								Tuer du	ng ng ng ng	1.2	
Transrectal											
Transvaginal								is disemple te	অধ্যাস্থ লাখন ভিত্ত	a de la compagna	
Transurethral											
Intravascular									and some	the Karasa Carthery	
Peripheral Vascular									**a		
Laparoscopic											
Musculo-skeletal Conventional									·		
Musculo-skeletal Superficial											
Other		<u></u>			<u> </u>	<u> </u>	<u> </u>	İ		L	

N=	new indication: P= previously cleared by FDA; E= added un	nder Appendix E
Ad	dditional Comments:	
Ap	oplicable combined modes: B+B; B+M	David h. Sym
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escription Us	V	Office of Device Evaluation (Sivision Sign-Off) Division of Reproductive, Abdomin

Prescription Use _____ (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number <u>K007357</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		Е	Е						Е	
Abdominal	-			-		ļ			. · · ·	
Audominai									•	
Intraoperative Abdominal		N	N						N issa asems	
Intraoperative Neurological										
Pediatric	1	E	Е					State of M	E. and the second second	
Small Organ (specify)		Е	Е					18,	E	
(specify) Neonatal Cephalic										ŀ
Adult Cephalic	1							and a state of the	n negerin in seesanta.	. 5., 1
Cardiac	<u> </u>							5 11 S 24	- Committee Section 1995	
Tranesophageal										
Transrectal	1	ļ						- Emilyano r	Message second	
Transvaginal								ting the section	4 tos	
Transurethral								stripper post	Justinia sekiri juri ya kirili ya kirili ya kirili ya kirili ya kirili ya kirili ya kirili ya kirili ya kirili	V V 4
Intravascular									. g juhn - Chan y sten	
Peripheral Vascular		E	E						E	a seed on the
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	1
Musculo-skeletal Superficial		N	N	·					N	
Other										

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)		
Applicable combined modes: B+B; B+M		Samil la Styron
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Prescription Use Per 21 CFR 801.109)	V	Divis	ision Sign-Off) sion of Reproductive, Abdominal, ENT, Radiological Devices k) Number <u>KOD2357</u>

N= new indication: P= previously cleared by FDA; E= added under Appendix \boldsymbol{E}

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal							,		•-	,),	
Intraoperative (specify)									44 4	es es succes	
Intraoperative Neurological								d	ort, , , , , , , , , , s speciff sits (f)	556. SEA	
Pediatric											
Small Organ (specify)		N	N					2281 1755.B&K	N	riyye . Mar	
Neonatal Cephalic											
Adult Cephalic								a Para est services	As whose we have a	and the state of t	
Cardiac	 							n sann i kwamba	and purpose of the state of the		
Tranesophageal							· ·	10 M/1 g 1 4 1 2 1			
Transrectal	\vdash	N	N						N		
Transvaginal		E	Е					198 . 6	regular and consequent	The second states	
Transurethral										. ,	
Intravascular	 								7.7 PROCESSOR	Medicine consider	
Peripheral Vascular						<u> </u>			-AV AV	No. 4 CAMPE	
Laparoscopic											
Musculo-skeletal Conventional									V 1-2-		
Musculo-skeletal Superficial							·		·	,	
Other		J			<u> </u>		l <u>.</u>	<u> </u>		<u> </u>	

Applicable combined modes: B+B; B+M	(1) -1 1 1.	
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N= new indication: P= previously cleared by FDA; E= added under Appendix E=

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

and Radiological Devices
510(k) Number <u>KCO</u>

Prescription Use (Per 21 CFR 801.109)

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		N	N	-					N	5 to 1 to 1 to 1
Intraoperative Neurological									i garanti da kaya ay da da k	
Pediatric		Е	E					ogravi i juga	ME or seek along depart	um specialise in spec
Small Organ (specify)		Е	Е						E	
Neonatal Cephalic		E	E						Е	
Adult Cephalic								May separate successive	Construction of the second	
Cardiac				1				was see a see a faasa see	an an in the contract of the second	
Tranesophageal										
Transrectal	-			1				an energy o	<u> </u>	<u>, e e e e e e e e e e e e e e e e e e e</u>
Transvaginal								i Water III	maday yadan sabi	
Transurethral	-							-3903e	Section of the Section Section (Section Section and the state	
Intravascular								4	n nena e Masa	
Peripheral Vascular Laparoscopic		N	N						N gerse	
- mpuroscopio					1					
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	,
Other										

N	= new	indicat	tion: P	≔ previ	ously	cleared	by	FDA;	E=adc	ded	under	Append	ix l	Ε
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Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

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510(k) Number_

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, Prescription Use_ and Radiological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E					`	E	,
Abdominal	<u> </u>	E	E						E ;	
Intraoperative Abdominal		E	E						E sanskala	,
Intraoperative Neurological									·	
Pediatric		E	Ε.					ds 400%	E e e e en en en en en en en en en en en	and supplies the supplies
Small Organ (specify)		Е	Е					,	E	
Neonatal Cephalic		Е	Е						E	
Adult Cephalic								7% ·	Land Committee Washington	an early to the Mar
Cardiac		N	N					1,11000	N	er til en en en en en en en en en en en en en
Tranesophageal	1									
Transrectal		Е	Е					. and ex.	E	
Transvaginal		Е	Е					Salas - War y	esj E or ordered	e ne takan da jakan dan
Transurethral								- W	e i va i i i i i i i i i i i i i i i i i	a distribution de la formación
Intravascular										
Peripheral Vascular		Е	E						E	V. 1 20 - 1 1 1.
Laparoscopic			1							
Musculo-skeletal Conventional	1	N	N						N	
Musculo-skeletal Superficial		N	N						N	•
Other	1		1							

N= new indication: P= previously cleared by FDA; E= added under Appendix E		
Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)		
Applicable combined modes: B+B; B+M	62-11	Ž,

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	Concurrence of CDRH, Office of Device Evaluation (ODE)
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Prescription Use	•		
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Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>K002357</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal		E.	E						E				
Abdominal		Е	E	<u> </u>					Е				
Intraoperative Abdominal									i da	Taratas so			
Intraoperative Neurological													
Pediatric		E	E						E				
Small Organ (specify)								. To A.P. Commission	a a a antiborismo	and a second			
Neonatal Cephalic	1												
Adult Cephalic	\dagger							v in departs	and the second second	1,0 1,1 1, 1,144			
Cardiac		N	N					to say, the two	N · · · · · · · · · · · · · · · · · · ·	d seed of the			
Tranesophageal								2 C 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	to the factor of Marginity (for				
Transrectal	†		1										
Transvaginal								and the server.					
Transurethral	-								ingraet, bourse				
Intravascular		 								sal and on the			
Peripheral Vascular						 				10 X Y			
Laparoscopic										2.54 %			
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other										<u></u>			

N- nove	indication:	P= previously	cleared by	FDA · F	= added under	Annendix F
N= new	indication:	r= previousiv	cleared by	TUA: E-	~ added under	Appendix E

Additional Comments:	Combined modes = $B+B$; $B+M$

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>K002357</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal		Е	E						E				
Abdominal		E	E						E .	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
Intraoperative (specify)									s Audi Tarin	e service de la constant			
Intraoperative Neurological													
Pediatric		E	Е					إيلامو عن الامار	*E	entre la la la companya			
Small Organ (specify)													
Neonatal Cephalic			T										
Adult Cephalic								1、初一大為門家鄉	r gegether a som en sign	all was the stage			
Cardiac									rija bili menekabua	4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
Tranesophageal									· WYSE W . W - SYTTEN				
Transrectal							<u> </u>						
Transvaginal									neus een neembestes	1 * 1			
Transurethral	1								าว เป็น	er Maria (partire) et el el			
Intravascular									remain Susuaro ma				
Peripheral Vascular							. A		the englished	, and the same of			
Laparoscopic													
Musculo-skeletal Conventional													
Musculo-skeletal Superficial										•			
Other				<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>				

Additional Comments: Applicable combined modes: B+B; B+M	
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Concurrence of CDRH, Office of Device Evaluation (ODE)

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>K00 235 7</u>

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal		E	Е						E				
Abdominal		Ė	Е						E ,				
Intraoperative (specify)									MARKET CO.				
Intraoperative Neurological													
Pediatric		Е	E					sala silentany	E compression	And the second section of the second			
Small Organ (specify)													
Neonatal Cephalic													
Adult Cephalic								4. 16 ₁ 7.12 ₁ 7.	in the Mayorian a	and always as a			
Cardiac		N	N					: ,,,,%,(%,4)44	N	e e e e e e e e e e e e e e e e e e e			
Tranesophageal								www.mangales	and the second				
Transrectal								1,000					
Transvaginal								1 to 1 september 1	denign the code	: \$			
Transurethral								14.1%	a tan Manusustotusa	Section of the second			
Intravascular									Karari eseriada	access to the contract of the			
Peripheral Vascular			 						megant for house				
Laparoscopic													
Musculo-skeletal Conventional							·						
Musculo-skeletal Superficial										•			
Other													

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Applicable combined modes: B+B; B+M	- Mei
Additional Comments:	
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N- new indication: P- previously cleared by PDA; E- added under Appendix E	

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K00735

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic									^				
Fetal													
Abdominal		E	E						E				
Intraoperative Abdominal		E	E						E sunsa	en en en en en en			
Intraoperative Neurological									gapas segj	1.1 .54.			
Pediatric		E	Е					رمواري داخر	E. REALIZADA	ing of the second			
Small Organ (specify)		Е	Е						Е				
Neonatal Cephalic		E	E					্জন হল গোলাই ছাইবারী	E	a trongsag			
Adult Cephalic								F	nation of the special section of the	tion times			
Cardiac	ļ												
Tranesophageal								consultant	11 (14) ASS (17)	1897 BO			
Transrectal								+ y Nev - x e. 4564	orani sittisi — ito oleh enga	and the second			
Transvaginal								the second constant		es trans			
Transurethral								dep.	, sundan sens	estation of the			
Intravascular									The title the Societies	, waster			
Peripheral Vascular		E	Е						Е				
Laparoscopic									ont seve	Parks (F.)			
Musculo-skeletal Conventional		· .							7				
Musculo-skeletal Superficial													
Other										L			

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast) Prescription Use (Per 21 CFR 801.109)
Applicable combined modes: B+B; B+M

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number KDD ABS

510(k) Number <u>KOO Z357</u>

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal		E	E						Е				
Abdominal		Е	E						E :				
Intraoperative (specify)						-			. (2-0,5-8)				
Intraoperative Neurological													
Pediatric		Е	E					Section Section 19	E CHANGE DELLA	tate in a section of			
Small Organ (specify)								and an other than	1 to 1 to 1 to 1 to 1 to 1 to 1 to 1 to	1381 H 1824 Light			
Neonatal Cephalic					<u> </u>	1							
Adult Cephalic								jajo (1. jajona), daga	n in the section of the	er syran er			
Cardiac								on of the section	ezgette jungag	er e e en en e			
Tranesophageal								out a reservação (1948)	unis spusient auch eile f	segito a liki muses			
Transrectal													
Transvaginal								en en en en en en en en en en en en en e	eren erene erene erene erene erene erene erene erene erene erene erene erene erene erene erene erene erene er	t total see			
Transurethral	<u> </u>							The Tenans	L 10 LNASSANAN				
Intravascular								ar say	e i to design	1 m 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -			
Peripheral Vascular	1								*** ·				
Laparoscopic													
Musculo-skeletal Conventional									****				
Musculo-skeletal Superficial				·						,			
Other					<u> </u>		1	<u> </u>					

Other							!				
N= ne	ew indication: P=	previous	ly cleared by	FDA; E= a	dded under A	ppendix E					
Addit	ional Comments:										
Appli	cable combined m		•					1/mis	la st	gm	
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rescription Use _ Per 21 CFR 801.	109)							and Radiolog		es	illiai, Eill I

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal													
Abdominal									i-				
Intraoperative (specify)										- 87			
Intraoperative Neurological	-												
Pediatric								1.5 (1.98)	, content 2 o como	Super States			
Small Organ (specify)		Е	E						E				
Neonatal Cephalic				1									
Adult Cephalic	ļ							et etgers ga	ر در در در در در در در در در در در در در	and the second			
Cardiac		<u> </u>							res e se se se se se se se se se se se se				
Tranesophageal													
Transrectal	T	E	E					, (a) (ii N) (a)	E	<u>ranka kane sa</u>			
Transvaginal		E	Е						E	er roughwesen			
Transurethral								11 11 11 11	Chales yet ka	19 (19)			
Intravascular								7.6	anners exemplicate	to the section			
Peripheral Vascular									and the second				
Laparoscopic													
Musculo-skeletal Conventional							·						
Musculo-skeletal Superficial													
Other								-					

	Superficial	1 1		1			1		}		1		
	Other												
	N= new indication: P= previously cleared by FDA; E= added under Appendix E Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)												
	Applicable combined mo	des: B+	B; B+N	M				S	find 6	a Season	~		
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Per 21 CFR	801.109)									r <u>K00</u> 2			

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										,
Fetal							,			
Abdominal		E	E						E	
Intraoperative Abdominal		E	E						E	
Intraoperative Neurological										
Pediatric		E	Е						E	
Small Organ (specify)		Е	Е					4.1	E	
Neonatal Cephalic										
Adult Cephalic			-							170
Cardiac										
Tranesophageal									i i dayay ka 1984	peo err i i internit
Transrectal	- 									
Transvaginal								in the second	n er som ess er	1.445.7
Transurethral										
Intravascular									n i nen yawan	
Peripheral Vascular		Е	E						Е	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	•
Other					1	<u> </u>		<u> </u>		1

N= new indication: P= previously cleared by FDA; E= added under Appendix E	
Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)	/
Applicable combined modes: B+B; B+M	David a Segum
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(Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>K002357</u>